

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

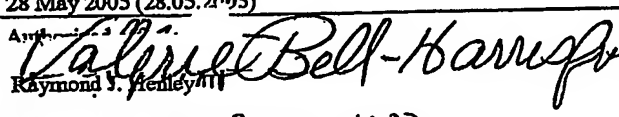
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 5166-PCT	FOR FURTHER ACTION	See Form PCT/IPPA/416
International application No. PCT/US04/24073	International filing date (day/month/year) 27 July 2004 (27.07.2004)	Priority date (day/month/year) 31 July 2003 (31.07.2003)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 38/28, 31/41, 31/44 and US Cl.: 514/4, 340, 342, 369, 376		
Applicant BAYER PHARMACEUTICALS CORPORATION		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☐ (sent to the applicant and to the International Bureau) a total of sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input checked="" type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

Date of submission of the demand 18 February 2005 (18.02.2005)	Date of completion of this report 28 May 2005 (28.05.2005)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	 Raymond J. Henley III Telephone No. 202-272-1600

Form PCT/IPPA/409 (cover sheet)(January 2004)

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/24073

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):

- ☒ the international application as originally filed/furnished
- ☒ the description:
 - pages 1-23 _____ as originally filed/furnished
 - pages* NONE _____ received by this Authority on _____
 - pages* NONE _____ received by this Authority on _____
- ☒ the claims:
 - pages 24-26 _____ as originally filed/furnished
 - pages* NONE _____ as amended (together with any statement) under Article 19
 - pages* NONE _____ received by this Authority on _____
 - pages* NONE _____ received by this Authority on _____
- ☐ the drawings:
 - pages NONE _____ as originally filed/furnished
 - pages* NONE _____ received by this Authority on _____
 - pages* NONE _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to the sequence listing (specify): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to the sequence listing (specify): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

Form PCT/IPEA/409 (Box No. I) (January 2004)

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. _____

PCT/US04/24073

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

- ☐ the entire international application
- ☒ claims Nos. Claim 19 has not been examined because a claim numbered as 19 was not present in

because:

- ☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require an international preliminary examination (*specify*):

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 19 are so unclear that no meaningful opinion could be formed (*specify*):

Claim 19 has not been examined because a claim numbered as 19 was not present in the application as filed.

- ☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

- ☐ no international search report has been established for said claims Nos. _____

- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

- ☐ has not been furnished

- ☐ does not comply with the standard

the computer readable form

- ☐ has not been furnished

- ☐ does not comply with the standard

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

- ☐ See Supplemental Box for further details.

Form PCT/IPEA/409 (Box No. III) (January 2004)

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/24073**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims <u>1-18 and 20-25</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>1-18 and 20-25</u>	YES
	Claims <u>NONE</u>	NO
Industrial Applicability (IA)	Claims <u>1-18 and 20-25</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and Explanations (Rule 70.7)

Claims 1-18 and 20-25 meet the criteria under PCT Article 33(2) for novelty because the prior art fails to teach the presently claimed (a) methods for treating or preventing (i) diabetes or diabetes-associated diseases/conditions, (ii) dementia or (iii) a cardiovascular disorder which include the step of administering an effective amount of, *inter alia*, an inhibitor of phosphodiesterase type-10A (PDE10A) to a mammal; (b) method for identifying compounds that would be useful for said methods; and (c) pharmaceutical composition comprising an effective amount of, *inter alia*, an inhibitor of PDE10A.

Claims 1-18 and 20-25 meet the criteria under PCT Article 33(3) for inventive step because the prior art fails to teach or suggest the presently claimed (a) methods for treating or preventing (i) diabetes or diabetes-associated diseases/conditions, (ii) dementia or (iii) a cardiovascular disorder which include the step of administering an effective amount of, *inter alia*, an inhibitor of phosphodiesterase type-10A (PDE10A) to a mammal; (b) method for identifying compounds that would be useful for said methods; and (c) pharmaceutical composition comprising an effective amount of, *inter alia*, an inhibitor of PDE10A.

Claims 1-18 and 20-25 meet the criteria under PCT Article 33(4) because the presently claimed (a) methods for treating or preventing (i) diabetes or diabetes-associated diseases/conditions, (ii) dementia or (iii) a cardiovascular disorder which include the step of administering an effective amount of, *inter alia*, an inhibitor of phosphodiesterase type-10A (PDE10A) to a mammal; (b) method for identifying compounds that would be useful for said methods; and (c) pharmaceutical composition comprising an effective amount of, *inter alia*, an inhibitor of PDE10A would have applicability in the medical industry.

NEW CITATIONS

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/24073

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

The application as filed is objected to under PCT Article 6 because a claim numbered as 19 is not present.